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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/525,998

03/15/2000

Rudolph Hauptmann

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09/26/2006

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EXAMINER

O'HARA, EILEEN B

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/525,998

Applicant(s)

HAUPTMANN ET AL.

Examiner

Eileen B. O'Hara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 68, 82 and 168 is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☒ Claim(s) 111 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 27,49,64,67,68,71-74,76,77,79,81-86,89-91,94,96,97,102,104,105,110,111,114,115,119,121-123,126,128,129,131-135,138,139,144-168,170,172 and 174-178.

Continuation of Disposition of Claims: Claims rejected are 27,49,64,67,71-74,76,77,79,81,83-86,89-91,94,96,97,102,104,105,110,114,115,119,121-123,126,128,129,131-135,138,139,144-167,170,172 and 174-178.

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DETAILED ACTION

Claims Status

1. Claims 27, 49, 64, 67, 68, 71-74, 76, 77, 79, 81-86, 89-91, 94, 96, 97, 102, 104, 105, 110, 111, 114, 115, 119, 121-123, 126, 128, 129, 131-135, 138, 139, 144-168, 170, 172 and 174-178 are pending in the instant application. Claims 97, 102, 104, 105, 110, 111, 114, 115, 119, 121-123, 126, 128, 129, 131-133, 135, 149-156, 158, 167, 168, 170, 172, 174 and 176 have been amended and claims 116 and 130 have been canceled as requested by Applicant in the Paper filed August 30, 2006.

Withdrawn Objections and Rejections

2. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 27, 49, 64, 67, 71-74, 76, 77, 79, 81, 83-86, 89-91, 94, 96, 97, 102, 104, 105, 110, 114, 115, 119, 121-123, 126, 128, 129, 131-135, 138, 139, 144-167, 170, 172 and 174-178

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remain rejected under 35 U.S.C. 102(e) as being anticipated by Wallach et al., U.S. Patent No. 5,695,953, effectively filing date Sept. 12, 1988.

Applicants traverse the rejection and assert that to support a rejection under 35 U.S.C. § 102, and state:

“the four corners of a single, prior art document (must) describe every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation.” In re Paulsen, 30 F.3d 1475, 1479 (Fed. Cir. 1994). The exclusion of even a single claimed element from a reference, no matter how insubstantial or obvious, is enough to negate anticipation. *Connell v. Sears, Roebuck & Co.*, 220 U.S.P.Q. (BNA) 193, 198 (Fed. Cir. 1983). The identical invention must also be shown in the single prior art reference in as complete detail as contained in the application against which the reference is cited. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1984). Moreover, the disclosure in an assertedly anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation. M.P.E.P. § 2121.01; *Elan Pharm., Inc. v. Mayo Found. for Med. Educ. & Research*, 346 F.3d 1051, 1054 (Fed. Cir. 2001); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F. Supp. 2d 69, 88 (17. Mass 2001) (citing *Akzo N.V. v. United States Int'l Trade Comm'n*, 808 F.2d 1471, 1479 (Fed. Cir. 1986)). A reference contains an "enabling disclosure" if the public was in possession of the claimed invention before the date of invention. M.P.E.P. § 2121.01. "Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his (or her) own knowledge to make the claimed invention." In re Donohue, 766 F.2d 531 (Fed. Cir. 1985)."

Applicants disagree with the Action's assertion that the '953 patent, which provides only a partial, incomplete amino acid sequence of a TNF inhibitory protein - and no nucleotide sequence whatsoever, anticipates the claimed invention. Applicants submit that because the '953 patent does not disclose any information about the nucleotide sequence of TNF binding protein (TNF-BP) – and discloses only fourteen of the first sixteen amino acid residues of a TNF inhibitory protein -, the '953 patent does not contain an enabling disclosure with respect to the instantly claimed invention. Applicants submit that even if the '953 patent disclosed the nucleotide sequence of its purified TNF-BP preparation – which it does not, the evidence clearly

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indicates that the '953 patent would not have disclosed an isolated nucleic acid molecule encoding a polypeptide comprising (or consisting of) the amino acid sequence as set forth in SEQ ID NO: 4. Applicants further submit that because the human urinary TNF-BP disclosed in the '953 patent does not constitute a single species as a result of the processing of the N-terminus of human urinary TNF in vivo, any nucleic acid molecule composition derived from the '953 patent's purified TNF-BP preparation would comprise multiple species, and in contrast, the nucleic acid molecules of the instantly claimed invention encode a polypeptide constituting a single species. Applicants discuss the evidence that the purification protocols described in the '953 patent and those described by Applicants are substantially similar, and the Applicants obtained a heterogeneous mixture of TNF-BP proteins from human urine, which resulted in a diffuse band which was due to the presence of a second polypeptide in a smaller amount, which is longer than TNF-BP at the end terminus. Amino acid sequence analysis revealed that only 80% of purified TNF-BP begins with ASP-41 of SEQ ID NO: 2, while a secondary sequence beginning with Leu-30 of SEQ ID NO: 2 was also detected (page 45), and therefore the TNF-BP purified from human urine is a mixture of at least two polypeptides whose N-terminus differs by 11 amino acids. Applicants submit that their purification protocol for human urinary TNF-BP is substantially similar to that described by the inventors of the '953 patent, and that Applicants' purification protocol incorporates the purification steps of Wallach et al. as well as an additionally, highly purified purification step. Applicants point to column 10 in the related '701 patent, in which Wallach et al. conceded that his preparation was "substantially purified" and that the "initial yield" from protein micro-sequence analysis was over "40%, indicating that the major protein in the preparation (the 27 kDa band) is related to the resulting sequence".

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Applicants contend that recombinant TNF-BP is not produced via processing of its N-terminus and therefore will not contain contaminants beginning with Leu-30 of SEQ ID NO: 2.

Applicants' arguments have been fully considered and are persuasive that the purified protein of Wallach et al. was a mixture of two TNF-BP's of different lengths. However, the claims read on the nucleic acid encoding various lengths of the TNF-BP. For example, claim 27 recites "An isolated nucleic acid molecule *comprising* the nucleotide sequence as set forth in SEQ ID NO: 3", so it encompasses the nucleic acid sequence encoding the full-length protein, or encoding more than one form of the soluble TNF-BP, which is present in Wallach et al.'s preparation from human urine. Even though Wallach et al. did not disclose a nucleic acid molecule that would encode a TNF-BP of SEQ ID NO: 4 of the instant application, because the claims of the '953 are drawn to nucleic acid, the Examiner is barred from allowing claims to the nucleic acid in the instant application. In addition, an issued patent is presumed valid. See the MPEP, 35 U.S.C. 282:

"Presumption of validity; defenses.

A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. Notwithstanding the preceding sentence, if a claim to a composition of matter is held invalid and that claim was the basis of a determination of nonobviousness under section 103(b)(1), the process shall no longer be considered nonobvious solely on the basis of section 103(b)(1). The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity."

If Applicants could amend the claims to distinguish over the nucleic acids of Wallach et

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al., the rejection would be withdrawn. For example, claims 68, 82, 111 and 168 are not anticipated by Wallach et al. because they encompass, for example, a nucleic acid encoding a polypeptide that consists of the amino acid sequence of SEQ ID NO: 4 and an amino-terminal methionine, and the nucleic acid of Wallach et al. would not have this sequence.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 147 and 164 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Wallach et al., U.S. Patent No. 5,695,953, and further in view of Shadle et al., U.S. Patent No. 4,847,325, filing date Jan. 20, 1988, for reasons of record in the previous office action.

Applicants traverse the rejection and submit that as the '953 patent cannot anticipate an isolated nucleic acid molecule for the reasons supra under the rejection under 35 USC § 102, the disclosure of the '325 patent does not compensate for the shortcomings in the '953 patent.

Applicants' arguments have been fully considered but are not deemed persuasive, for the reasons discussed supra in the rejection under 35 USC § 102.

It is believed that all pertinent arguments have been answered.

Conclusion

5.1 Claims 68, 82 and 168 are allowed.

5.2 Claim 111 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5.3 Claims 27, 49, 64, 67, 71-74, 76, 77, 79, 81, 83-86, 89-91, 94, 96, 97, 102, 104, 105, 110, 114, 115, 119, 121-123, 126, 128, 129, 131-135, 138, 139, 144-167, 170, 172 and 174-178 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nichol can be reached at (571) 272-0835.

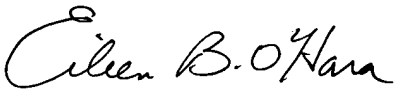
The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://portal.uspto.gov/external/portal/pair>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Eileen B. O'Hara, Ph.D.

Patent Examiner


EILEEN B. O'HARA
PRIMARY EXAMINER